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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/115,832	07/15/1998	REINHARD EBNER	PF399	1845

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EXAMINER

HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 12/04/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/115,832

Applicant(s)

EBNER et al.

Examiner

Fozia Hamud

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1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 14, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-38 and 41-48 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 38, and 41-48 is/are rejected.
- 7) ☒ Claim(s) 24-37 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

1. Receipt of Applicant's arguments in Paper No.20, filed 9/14/01 is acknowledged.
2. Claims 23-38, 41-48 are pending and are under consideration by the Examiner.

Priority

Applicants claim priority to the provisional application with the serial number 60/052870 filed on 16 July 1997. On page 10, lines 1-10, Applicants describe the instantly claimed nucleic acid to be contained in clone HTSGS30. It is noted that in the provisional application, Applicants describe clone HTSGS30 as corresponding to the polynucleotide of SEQ ID NO:3 encoding the protein of SEQ ID NO:13, (see table 1 on page 54 of 60/052870). Instant claims are drawn to an isolated polynucleotide encoding SEQ ID NO:2. SEQ ID NO:1 of the instant Application comprises 705 bases and encodes SEQ ID NO:2 which comprises 180 amino acid residues. SEQ ID NO:3 of the provisional application comprises 723 bases and seems to encode a protein that comprises 127 amino acid residues. It appears that the instantly claimed polynucleotide encoding SEQ ID NO:2 was not disclosed in the parent application. Accordingly, the effective filing date of this application is 15 July 1998 and not 16 July 1997, since this application is not eligible to get the benefit of the filing date of the provisional application.

Specification

3. The Brief Description of the Drawing describes Figure 1 as showing the deduced amino acid sequence of SEQ ID NO:2, where the methionine residue of the beginning of the leader sequence is

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shown in position number 1, whereas, the leader positions in the corresponding sequence of SEQ ID NO:2 are designated with negative position numbers, (see page 7, lines 6-13). Thus, the leader sequence positions 1-20 in Figure 1, should correspond to positions -20 to -1 in SEQ ID NO:2, however, the leader sequence in both Figure 1 and SEQ ID NO:2 is shown in positive position numbers (i.e, both the figure and SEQ ID NO:2 designate the beginning methionine with positive number 1, thus both comprise 1-180 amino acid residues). On page 11, lines 10-11, of the instant specification, applicants describe the mature protein as being shown in positions 1-160 of SEQ ID NO:2, which appears that the last 20 amino acids of SEQ ID NO:2 are excluded. Clarification is requested.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 U.S.C. §112, first paragraph

5a. Claims 23, 38 and 41-48 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record set forth in the office action that was mailed on 17 May 2001, pages 2-3.

Applicants argue that one skilled in the art could reasonably conclude that Applicants had possession of the claimed nucleotides, because the specification describes the method by which the instant mature form was determined. The specification teaches that the ATCC Deposit No. 209232 contains a plasmid that contains the full-length IL-20 cDNA and the expression of said deposit would *inherently* produce the mature polypeptide. Applicants also argue that the Examiner has provided no evidence that there are any mature proteins that would differ from the those disclosed in the specification.

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Applicants arguments have been fully considered, but are deemed unpersuasive. Although Applicants teach a general methodology of how to obtain the claimed mature protein, they do not describe the structure of the mature protein and the skilled artisan would not be able to visualize the structure of said mature solely based on the method of obtaining it. With respect to the argument that the expression of the deposited clone would inherently produce the mature form, Applicant is reminded that it is not the plasmid but the host cell that processes and cleaves the signal sequence, therefore, the protein would be differentially processed depending on the host cell in which it is expressed. Finally, with respect to Applicant's last argument, the issue at hand is not an enablement issue, but rather a written description one, therefore, the burden is not on the Examiner to prove the existence of other mature proteins, the burden is on the Applicants to describe what is claimed. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Adding structural limitation of the mature protein in claim 23, (O) would obviate this rejection.

Conclusion

- 6a. Claims 23-48 are not allowed.
- 6b. Claims 24-37 are objected to as being dependent upon the rejected base claim 23, but would be allowable if rewritten in independent form.

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7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Group 1647
28 November 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud